TRANSDUCER MOUNTING ASSEMBLY

This application claims benefit of the filing date of U.S. Provisional Application Serial No. 60/242,994, filed October 25, 2000, the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to an apparatus for adjustably mounting an ultrasonic transducer to an orthopedic appliance, wherein the transducer can be adjustably positioned in a manner appropriate for ultrasonic therapy.

2. Description of Related Art

The use of ultrasound therapy for the acceleration of healing of bone injuries is known in the art. Similarly, the acceleration of healing of soft tissue injuries, particularly musculoskeletal tissues, by the application of ultrasound has also been described. Ultrasonic therapy generally involves placing an ultrasonic transducer, usually associated with a conductive gel or bladder, against or near the skin in the vicinity of the injury, and driving the transducer with a signal generator, so that the transducer delivers ultrasonic waves within a particular range of therapeutically effective frequencies for a period of time and for a sufficient number of applications to achieve effective results in accelerating healing. See, e.g., U.S. Patent Nos. 6,273,864; 6,190,336; 5,762,616; and 5,520,612, the entire contents of each of which are incorporated herein by reference.

Ultrasonic therapy can be particularly useful in treating injuries, such as severe fractures or soft tissue injuries and the like, that require either support or immobilization of a joint or immobilization of bones relative to each other at a fracture site, using some form of orthopedic appliance.

These types of injuries are often treated by the application of a brace, fixator, cage, or other orthopedic appliance to the site of the injury to immobilize the affected area or to limit the range of motion during healing, e.g., occurring after orthopedic surgery. Placement of ultrasonic transducer heads in positions most appropriate for accelerating healing may be impeded by elements of the orthopedic appliance when existing attachment techniques, such as straps or bandages, are used.

In addition, ultrasonic treatment is often of great benefit in speeding healing by patients that have been discharged from the hospital and are convalescing. The frequency of treatments and the difficulty patients often have with locomotion make home treatment desirable. As a result, ultrasonic treatment is often self-administered by the patient following physician instruction in use of the device. However, existing attachment techniques rely on patient compliance in accurately positioning the transducer. Because patients can be inconsistent in positioning the transducer, applying conductive gel to the proper location, etc., there exists a need in the art for a mechanism for adjustably mounting an ultrasonic transducer to an orthopedic appliance so that the transducer can consistently and reliably be brought into contact with the desired treatment site without interfering with or interference from the appliance.

SUMMARY OF THE INVENTION

The apparatus of the invention allows an ultrasonic transducer to be secured to an orthopedic appliance in an adjustable fashion, so that the transducer can be consistently and reliably moved into the proper position for treatment, without interference from or interfering with the elements of the orthopedic appliance, and then can be moved out of the way or removed during periods between treatments.

In one embodiment, the invention relates to an apparatus for adjustably securing an ultrasonic transducer to an orthopedic appliance, having:

(a) an optional adjustable clamp adapted to adjustably secure the apparatus to an element of an orthopedic appliance;

(b) a transducer holder adapted to secure the transducer to the apparatus;

(c) an adjustable connector adapted to adjustably connect the optional adjustable clamp to the transducer holder.

The configuration of the optional adjustable clamp may take various forms in order to allow the apparatus to be secured to a variety of orthopedic appliances.

As described in more detail below, the apparatus may take the form of one of several alternative embodiments, each of which allow attachment to one or more elements of existing orthopedic appliances, and allow the ultrasonic transducer to be adjustably and reliably positioned relative to the patient.

BRIEF DESCRIPTION OF DRAWINGS

FIG. 1 is an exploded perspective view of the apparatus of one embodiment of the invention secured to an element of an orthopedic appliance.

FIG. 2 is a perspective view of two embodiments of the invention secured to an external ring fixator.

FIG. 3 is an enlarged perspective view of the apparatus of one of the embodiments of the invention shown in FIG. 2, secured to an external ring fixator.

FIG. 4 is a perspective view of one embodiment of a transducer holder according to the invention.

FIG. 5 is a perspective view showing two embodiments of the apparatus of the invention secured to an external ring fixator.

FIG. 6 is a perspective view of another embodiment of the apparatus of the invention.

FIG. 7 is an exploded perspective view of the embodiment of the invention illustrated in FIG. 6.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

The apparatus of the invention is intended to be attachable to a variety of orthopedic appliances, ranging from external fixators, such as Ilizarov rings, unilateral fixators, or spatial frames (such as those disclosed in U.S. Patent Nos. 6,030,386; 5,971,984; 5,891,143; 5,728,095; and 5,702,389, the entire contents of each of which are incorporated herein by reference), to orthopedic braces and the like. As a result, the particular configuration of the adjustable clamp may be substantially variable. It may be adjustable in the sense that it can be attached to the orthopedic appliance in a variety of locations or positions, or in the sense that the clamp allows movement relative to the element of the orthopedic element to which it is attached, or in the sense that the attachment point of the clamp to the adjustable connector can be varied, or some combination thereof. The adjustable clamp may, in fact, be available or sold with the orthopedic appliance itself, and in that sense is optional.

As an example, when the apparatus of the invention is to be affixed to the ring of an external ring fixator, a fixator clamp, also known as a "Rancho cube," may be used to adjustably clamp the apparatus to the ring. Another example of an adjustable clamping mechanism includes one or more hinges, which may be used to secure the device to various points on rods or other rigid elements of the orthopedic appliance, such as the rods of a ring fixator. These hinges may allow movement of the adjustable connector relative to the attachment point as the hinges rotate. Other examples of suitable clamps include bolts, screw clamps, spring clamps, standard laboratory clamps, and the like, whose position on the orthopedic appliance may be varied.

The transducer holder is adapted to attach the transducer to the device. It may be removable from the transducer, such as a cap into which the transducer may be inserted, or it may be permanently affixed to the transducer. The transducer holder may be a threaded opening in or threaded stud mounted on a nonoperative surface of the transducer, with which a correspondingly threaded stud or threaded opening on or attached to the adjustable connector may be inserted. Other arrangements include non-threaded openings/studs secured by set screws and the like, ball-and-socket joints affixed to a nonoperative transducer surface, and the like.

The adjustable connector provides, in effect, an adjustable link between the transducer holder and the adjustable clamp. The connector may be adjustable in the sense that the attachment point of the adjustable clamp can be varied, or in the sense that the attachment point of the transducer holder may be varied, or in the sense that the connector itself contains moveable parts whose positioning can be adjusted, or in the sense that the connector allows the transducer and transducer holder to be removed when not in use, or any combination of these. In any event, the connector allows for the position of the transducer holder, and thus of the transducer, to be varied relative to the adjustable clamp.

One example of an adjustable connector is a plate, which may be substantially flat or which may be angled, having one or more slots for adjustable attachment of the adjustable clamp, the transducer holder, or both. Another example is an articulating arm, attached through an adjustable bracket, a threaded stud/opening arrangement, or a ball-and-socket joint, to the transducer holder at one end, and bolted or clamped to an element of the orthopedic appliance at the other end. This articulating arm may be made from a flexible articulated material having a plurality of joints, or may be made from a few rigid elements having swivel joints and lockable slide collars. Another example of an adjustable connector includes a shaft secured to the transducer holder on one end and having an optional handle at the other end, which is disposed in a barrel assembly which allows the shaft to move within the barrel, and which barrel assembly contains a pin which can be adjustably secured by the clamp.

The invention will be further described by reference to certain of its specific embodiments illustrated in the accompanying drawings. This description and the drawings are not intended to be limitative of the appended claims.

FIG. 1 shows an embodiment of the invention wherein optional adjustable clamp contains hinge 10, which is rotatably attached to an element of an orthopedic appliance 20. Hinge 10 is adjustable because it can rotate about the longitudinal axis of element 20, and may optionally also be moveable along its length. Hinge 10 can be adjustably secured to adjustable connector 30 by a fastener 40, illustrated as a threaded bolt and nut combination. The fastener 40 passes through hole 50 in hinge 10, and then passes through slot 60 in first leg 70

of the adjustable connector 30. This allows the location of the hinge 10 along the first leg 70 to be adjusted by sliding fastener 40 along slot 60 and tightening the fastener when the hinge 10 and adjustable connector 30 are in the appropriate relative position.

Transducer holder 80 comprises a plate affixed to transducer 90 and fastened to second leg 100 of adjustable connector 30 by a fastener 120, which passes through hole 130 in plate 80, and which also passes through slot 110 in second leg 100. The fastener illustrated is a bolt which is secured by a correspondingly threaded nut (not shown) after passing through slot 110. It will be recognized that any fastener that can be tightened, loosened, and retightened securely will function to provide the desired adjustability in securing the transducer holder to the adjustable connector, and in securing the clamp to the adjustable connector. As illustrated, adjustable connector 30 contains an opening 150 to accommodate a cable 140 powering the transducer 90.

As illustrated, adjustable connector 30 is a rectangular, angled plate having two legs approximately perpendicular (oriented at about 90°) relative to each other. It will be recognized that other shapes and orientations may be used and still fall within the spirit and scope of the invention. For example plates that are circular or oval or have another geometrical shape, or that are angled at acute or obtuse angles, or that are substantially flat, could also be used in the invention.

An example of an embodiment of the invention using a flat plate 230 as the adjustable connector between transducer holder 240 and clamp 210 is shown in FIG. 2. Clamp 210, as illustrated, secures the apparatus of the invention to an element of an external ring fixator.

Also illustrated in FIG. 2 and FIG. 3, and shown secured to a ring 270 of an external ring fixator, is another embodiment of the apparatus of the invention wherein the adjustable connector comprises a flexible arm 250, which connects clamp 260 to transducer holder 280. As illustrated, flexible arm 250 is a multi-jointed flexible articulating arm. Suitable materials for such a flexible articulating arm include MEDIFLEX ® (Flexbar Machine Corp.), Lockline flexible arm materials, or other flexible arm materials or "goosenecks." It is generally desirable that these articulating arms be lockable, so that once oriented, their

reorientation requires application of suitable force. This allows for adjustability but also helps to prevent the arms from being inadvertently knocked out of position during treatment. It is also desirable that the articulating arm be such that additional articulating joints can be added to the arm or removed from the arm as needed, in order to adjust the length of the arm as necessary to treat a particular injury.

Suitable transducer holders for use in connection with this embodiment of the invention include a ball-and-socket joint affixed to the non-operative surface of the transducer (or to a cap into which the transducer can be inserted), and capable of attachment to, and articulation with, the flexible arm. An alternative embodiment of transducer holder is shown in FIG. 4, which shows a bracket 290 attached to flexible arm 250 and also attached to a transducer or cap for holding a transducer by suitable fastener 300 (e.g., a bolt, screw, or rivet). Desirably, the transducer-holder is capable of holding an EXOGEN 3000 brand transducer or a similar transducer.

As illustrated in FIG. 2 and FIG. 3, a wingnut is used to clamp one end of the flexible arm to the ring of the fixator; it will be recognized that a hinged clamp, such as that shown in FIG. 1, could also be used to clamp the articulating arm to a vertical rod of the fixator ring, or to a unilateral fixator or an orthopedic brace within the scope of the invention. Alternatively, a no-hole clamp, such as that shown in FIG. 5, which does not rely on the presence of holes in the ring, or spring clamps, standard laboratory clamps, screw clamps, or other clamp mechanisms could be used to secure the apparatus to the orthopedic appliance.

FIG. 5 also illustrates an alternative configuration for the apparatus of the invention, wherein a clamp 260 is used to secure the apparatus to a ring of an external fixator, which may be any of the clamp mechanisms described above for use with a flexible articulating arm. Instead of the multi-jointed flexible articulating arm described above, this configuration uses an articulating arm 310 having a first swivel joint 320 adapted to be secured by clamp 260 and attached to slide collar 330. Slide collar 330 can be adjustably positioned along rod 340, which is attached to second swivel joint 350, which is adapted to attach to transducer holder 280, which may be a threaded stud adapted to be inserted into a

correspondingly threaded opening on the nonoperative surface of the transducer, or of a cap into which the transducer may be inserted.

FIG. 6 is a perspective view of another embodiment of the apparatus of the invention, and FIG. 7 provides an exploded perspective view of this embodiment. Transducer holder 280 is a cap adapted to receive the transducer and hold it in place, either by press fitting or by means of a set screw, and to attach to adjustable connector 400 by shaft 410. Shaft 410 moves in barrel 420, so that the position of transducer holder 280 relative to adjustable connector 400 can be varied. Adjustable connector 400 also contains pin 430, illustrated as extending orthogonally to barrel 420, which is adapted to be received by a clamp (not shown) and adjustably secured thereby. Desirably, pin 430 is sized and configured so as to be securable by a standard fixator or other clamp, such as a rancho cube, where it can be secured by a set screw at the desired level of the cube after being rotatably positioned. The location of the cube on the orthopedic appliance can also be varied or adjusted, providing additional flexibility in use. Alternatively, the pin can be threaded and screwed onto a ring of an external ring fixator using a wingnut or other fastener. Most desirably, the pin may be threaded, but sized to fit a rancho cube, enabling the apparatus to be secured in a variety of ways to a variety of elements of the orthopedic appliance.

In addition, shaft 410 and barrel 420 may be correspondingly threaded, so that the position of shaft 410 in barrel 420 may be adjusted by rotating shaft 410 relative to barrel 420. Alternatively, as illustrated, adjustable connector 400 may contain a biasing element 440 (illustrated as a coil spring disposed around the shaft 410) to urge the transducer holder away from the barrel and against the body of the patient. Optional handle 450 is provided in the illustrated embodiment for ease of adjustment of the apparatus. If the shaft and barrel are threaded, turning the handle will move the threaded shaft relative to the barrel, and allow adjustment of the position of the transducer holder relative to the patient. If a biasing element is present, the transducer can be moved by pulling the shaft against the biasing force exerted by the biasing element and locking the shaft in this retracted position (engaging optional locking pin 460 with optional locking slot 470, shown in FIG. 7) or by releasing the shaft when the transducer is appropriately positioned relative

to the patient, so that the biasing element forces the transducer against the patient during treatment.

As illustrated, adjustable connector is optionally jointed at joint 480 (FIG. 6) in order to allow pin 430 to remain positioned appropriately in the adjustable clamp, while the remainder of adjustable connector 400 is removed between treatments or for adjustment or repair. This joint is illustrated as a male D-element (a male element having a D-shaped cross section) on the barrel side of the adjustable connector, which corresponds to a female D-element (a female element having a D-shaped cross section) on the pin side of the adjustable connector. Retaining ball 500 holds the joint in place until the two sides of the adjustable connector are forced apart. It will be recognized that, if this removability feature is not desired or necessary, joint 480 can be eliminated from the apparatus, and that different joint configurations can be used, as long as they perform the function of removably attaching the transducer holder to the pin without allowing the joint to rotate, or the apparatus to rotate once it is secured in the clamp.

The invention also relates to a method of using the device described above. The device, or a portion thereof, can be attached to an orthopedic appliance, typically to a rigid element of the orthopedic appliance, via the clamp. The transducer can be attached to the transducer holder (if detachable) and the clamp, adjustable connector, and optionally the transducer holder adjusted to the appropriate orientation to deliver suitable ultrasound therapy. The adjustability of the device allows the transducer to be consistently and reliably positioned at the appropriate location without interference from or with the orthopedic appliance. Ultrasonic therapy can be delivered, and the device moved away from the treatment site and optionally detached (in some embodiments) from the appliance. Alternatively, the transducer can be removed from the device if desired.